First Patients Dosed in Phase 1 Clinical Study of ImmunityBio's CAR-NK Cell Therapy for the Treatment of Relapsed B-Cell Non-Hodgkin Lymphoma

October 24, 2024

- Company's first clinical trial studying CAR-NK (CD19 t-haNK) cellular therapy in liquid tumors
- First natural killer cell-based cellular therapy study conducted in the continent of Africa
- Complete enrollment currently expected in Q1 2025

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 24, 2024-- Immunotherapy innovator ImmunityBio, Inc. (NASDAQ: IBRX), announced today that the first patients have been dosed in an initial trial studying the potential of the company's CAR-NK cell therapy targeting CD-19 in the treatment of non-Hodgkin's lymphoma (NHL). In the QUILT 106 trial, CD19-targeted high-affinity natural killer (t-haNK) cells are being tested initially as a single agent, and after demonstrating safety, then in combination with standard NHL treatment rituximab, in participants with selected CD19+ and CD20+ relapsed/refractory B-cell NHL. The phase 1, open label clinical study is designed to enroll up to 10 participants and is being conducted in Johannesburg, Pretoria, and Bloemfontein, South Africa.

This is the first cellular-targeted natural killer (NK) cell therapy study ever to be conducted in South Africa, and is designed to provide important clinical information on a cancer with a significant rate of diagnosis in the region, but with few treatment options. Non-Hodgkin's lymphoma is the 6 th most common malignancy among people in Sub-Saharan Africa and it is the 4th most diagnosed cancer in men and the 5th most diagnosed cancer in women in South Africa, according to the Cancer Association of South Africa.

"This trial is important for ImmunityBio as our first clinical study of our CAR-NK, CD19 t-haNK cell line, as well as one of our first studies in liquid tumors," said Patrick Soon-Shiong, M.D., Executive Chairman, Founder and Global Chief Scientific and Medical Officer at ImmunityBio. "We have chosen to undertake this trial because Sub-Saharan African and, in particular, South African populations are often overlooked when it comes to advanced clinical research, despite the need for innovative immunotherapies in the region."

Full patient enrollment in this Phase 1 study of CD19 t-haNK is currently expected in the first quarter of calendar year 2025 with topline data readout expected in the second half of the calendar year 2025.

This study, being conducted in South Africa, is similar to ImmunityBio's U.S.-based trial QUILT 3.092, a phase 1 open-label study of CD19 t-haNK as a single agent and in combination with the company's IL-15 superagonist (N-803; ANKTIVA®) and rituximab in participants with relapsed or refractory NHL.

About the QUILT 106 Study

The Phase 1, first-in-human (FIH), open-label study is designed to enroll up to 10 participants at sites in Johannesburg, Pretoria, and Bloemfontein, South Africa with the primary endpoint of the trial to evaluate the safety and preliminary efficacy of CAR-NK, CD19 t-haNK as a single agent and in combination with rituximab in participants with selected CD19+ and CD20+ R/R B-cell non-Hodgkin lymphoma (NHL). Participants will initially receive a single 3-week cycle of the CD19 t-haNK as a single-agent regime. Following a 1-week safety pause, participants will then receive a 3-week cycle of CD19 t-haNK in combination with rituximab. Patients will undergo multiple assessments of safety and efficacy to help evaluate the safety of CD19 t-haNK as a single agent and in combination with rituximab in participants with R/R NHL, who have active disease after completing ≥ 2 lines of cytotoxic chemotherapy.

About CAR-NK, CD19 t-haNK

CD19 t-haNK is a human, allogeneic, stable clonal NK cell line generated from the parental activated NK (aNK) cell line (NK-92). Based on the demonstrated therapeutic efficacy of chimeric antigen receptor (CAR) targeting and on the important role of FcγR-mediated antibody-dependent cellular cytotoxicity (ADCC) in the effectiveness of therapeutic IgG1 monoclonal antibodies, it was hypothesized that modification of the parental aNK cell line to stably express both a CD19-targeted CAR and the high-affinity variant of CD16 would result in potent and selective antitumor activity. Therefore, the novel CD19 t-haNK cells have been genetically engineered to stably express 3 main proteins: (1) a human CD19-targeted CAR; (2) the high-affinity variant of the human Fcγ receptor (FcγRIIIa/CD16a 158V) for enhanced ADCC; and (3) endoplasmic reticulum-retained version of human interleukin-2 (ERIL-2) for independent growth.

Non-Hodgkin Lymphoma

Non-Hodgkin lymphoma (NHL) is a heterogeneous disease that most commonly originates in B lymphocytes. In 2020, according to the South Africa National Cancer Registry (SANCR 2020), it is estimated that 1 in 174 men and 1 in 288 women will develop NHL. According to Global Cancer Observatory (Sung 2021), the incidence of NHL is 4.1% of all cancers. A comparative study of the distribution of NHL subtypes in South Africa reported that Southern Africa had a significantly lower proportion of low-grade B cell NHL (34.3%) and a higher proportion of high-grade B cell NHL (51.5%) compared to Western Europe (54.5% and 36.4%) and North America (56.1% and 34.3%) (Perry 2015).

About ImmunityBio

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy and cell therapy platforms, alone and together, act to drive

and sustain an immune response with the goal of creating durable and safe protection against disease. Designated an FDA Breakthrough Therapy, ANKTIVA® is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer CIS that activates natural killer cells, T cells, and memory T cells for a long-duration response. The company is applying its science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases. For more information, visit www.immunitybio.com and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding clinical trial plans and timing, patient enrollment and treatment, timing of data read outs, market and prevalence data, the regulatory review process and timing thereof, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, potential future uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this presentation that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "is," "seeks," "should," "will," "strategy," and variations of such words or similar expressions. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, (i) risks and uncertainties regarding clinical trial patient enrollment and timing and potential results, including with respect to the trial described herein, (ii) risks and uncertainties related to the regulatory submission and review process, (iii) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (iv) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process, (v) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (vi) potential delays in product availability and regulatory approvals, (vii) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (ix) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (x) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies. More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 19, 2024 and the Company's Form 10-Q filed with the SEC on August 12, 2024, and in subsequent filings made by ImmunityBio with the SEC, which are available on the SEC's website at www.sec.gov. ImmunityBio cautions you not to place undue reliance on any forward looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information in this press release, except to the extent required by law.

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Source: ImmunityBio, Inc.